

**Notice of Allowability**

Application No.

10/761,201

Examiner

Ginny Portner

Applicant(s)

BOREN ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/27/07.
2. ☒ The allowed claim(s) is/are 2,4,7,9,28,32-33; now claims 1-7.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/202,178.
3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application   |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>attached hereto</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                                |
|  | 9. <input type="checkbox"/> Other _____.  |

### EXAMINER'S AMENDMENT

1. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on February 27, 2007 requested an extension of time for 2 MONTH(S) and authorized the Director to charge Deposit Account No. 02-2448 the required fee of \$450 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

1. **Canceled.**

~~2.~~ **(Currently Amended)** A test kit comprising a monospecific antisera that recognizes a BabA antigen and comprises an immunoglobulin that binds said BabA antigen via a variable region, wherein said Bab A adhesin protein comprises SEQ ID NO:5 and is produced using an isolated and purified bacterial blood group antigen binding protein (BabA) from *Helicobacter pylori* species, wherein said BabA protein binds specifically to fucosylated Lewis<sup>b</sup> type I and H-1 blood group antigen-glycoconjugates and,

wherein said BabA protein contains less than 20% bacterial protein impurities, has a molecular weight in the interval of ~~703~~ to ~~775~~ kDa as determined by sodium dodecyl sulphate-polyacrylamide gel electrophoresis (SDS-PAGE), and is not a HopA, HopB, HopC, HopD, or HopE protein.

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3. Canceled

2 4. (Currently Amended) The ~~immunoglobulin composition~~ test kit according to claim ~~23~~<sup>1</sup>, wherein said BabA adhesin protein has a molecular weight in the interval of about ~~730~~ to ~~757~~ kDa as determined by SDS-PAGE.

5. Canceled

6. Canceled.

6 4 7. (Currently Amended) The test kit according to claim ~~32~~<sup>4</sup> ~~antibody according to claim 6~~, wherein said BabA adhesin protein has a molecular weight in the interval of about ~~730~~ to ~~757~~ kD as determined by SDS-PAGE.

8. Canceled.

7 9. (Currently Amended) The test kit according to claim ~~32~~<sup>4</sup> ~~antibody according to claim 6~~, wherein said ~~antibody~~ immunoglobulin is a monoclonal antibody.

10. Canceled.

11. Canceled

12. Canceled

13. Canceled

14. Canceled

15. Canceled

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16. **Canceled**

17. **Cancelled**

18. **Cancelled**

19. **Canceled**

20. **Cancelled**

21. **Cancelled**

22. **Canceled**

23. **Canceled**

24. **Canceled**

25. **Canceled**

26. **Canceled**

27. **Canceled**

328. **(Currently Amended)** The ~~composition~~ <sup>1</sup>test kit according to claim ~~2/4~~ <sup>1/4</sup>, wherein the molecular weight of said BabA adhesin protein is about 73.5 kDa.

29. **Canceled**

30. **Canceled**

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**31. Canceled**

32. (NEW) A test kit comprising an isolated monospecific immunoglobulin composition that recognizes a BabA antigen and comprises an immunoglobulin that binds said BabA antigen via a variable region, wherein said Bab A adhesin protein comprises SEQ ID NO:5 and is produced using an isolated and purified bacterial blood group antigen binding protein (BabA) from *Helicobacter pylori* species, wherein said BabA protein binds specifically to fucosylated Lewis<sup>b</sup> type I and H-1 blood group antigen-glycoconjugates and,

wherein said BabA protein contains less than 20% bacterial protein impurities, has a molecular weight in the interval of 70 to 77 kDa as determined by sodium dodecyl sulphate-polyacrylamide gel electrophoresis (SDS-PAGE), and is not a HopA, HopB, HopC, HopD, or HopE protein.

33. (NEW) The ~~antibody~~ immunoglobulin according to claim 32, wherein the molecular weight of said BabA adhesin protein is about 73.5 KDa.

***Reasons for Allowance***

2. The following is an examiner's statement of reasons for allowance: The claimed invention as amended no longer reads post translationally modified monospecific colostrum antibodies, as these antibodies would not bind to BabA by the variable region, but bind by the Fc-constant region of the antibody. Additionally, the claimed invention no longer reads on an anti-id antibody that presents the Lewis-B antigen in the variable regions, the prior art does not teach not reasonably suggest the formulation of the antibody into a test kit, nor does it suggest binding to a protein that comprises the amino acid sequence of SEQ ID NO 5. The instantly claimed invention directed to a test kit that comprises a monospecific antisera (independent claim 2) or a monospecific immunoglobulin (independent claim 32) that recognizes a BabA

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antigen by the variable region, and said BabA antigen comprises the amino acid sequence SEQ ID NO 5, is not taught nor reasonably suggested by the prior art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp March 1, 2007



MARK NAVARRO  
PRIMARY EXAMINER